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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/922,559 | 08/03/2001 | Jon E. Beck | IOM-P022.01 | 1726 |

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EXAMINER

SIRMONS, KEVIN C

ART UNIT PAPER NUMBER

3763

DATE MAILED: 07/25/2003

8

Please find below and/or attached an Office communication concerning this application or proceeding.

N,K

| | | | |
|------------------------------|-------------------------------|-----------------------------|--|
| Office Action Summary | Application No. 09/922,559 | Applicant(s) BECK ET AL. | |
| | Examiner Kevin C. Sirmons | Art Unit 3763 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 09 May 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6, 9-15, 18, 20-26 and 29 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 9-15, 18, 20-26 and 29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 112

Claims 6 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 6 and 15 recite the limitation "the biasing." There is insufficient antecedent basis for this limitation in the claim. (Second Time) Applicant has not addressed nor corrected this rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 9-15, 18, 20-26 and 29 are rejected under 35 U.S.C. 102(b) as being anticipated by Bosniak et al U.S. Pat. No. 5,169,384.

Bosniak discloses an iontophoretic apparatus comprising: a housing member (20); a current distribution member (50) associated with the housing member; a medicament containment member (54) associated with the current distribution member; a handle member (32) associated with the housing member, the handle member including: a lateral straddling member (32A); a medial straddling member (32B); (note: Applicant merely has several reference numerals such as (20, 25, 46, 72 etc.) all indicating the same part,

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which is the handle member (18). Applicant has not placed any structural limitations in the claims that would differentiate his device over the prior art of record.); and wherein at least one of the lateral straddling member (32A) and the medial straddling member (32B) includes means for registering/maintaining (32) the placement of the straddling member within one or more of a region encompassed by a lateral angle of an eye, a region encompassed by a medial angle of the eye, a lacus lacrimalis of the eye and a caruncula lacrimalis of the eye to, in turn, secure placement of the housing member adjacent the same eye (fig. 1); as to claim 2, (32A and 32B see above note indicating several reference numerals indicating the same part); as to claim 3, at least one of the first and second handle regions (32A, 32B) including a gripping region (not numbered; however, clearly seen in fig. 1), the gripping region facilitating the grasping of the handle region by a user (col. 6, lines 18-23); as to claim 4, (fig. 1); as to claim 5, (the straddling members (32A, 32B) can be adjusted so that they facilitate retention of an eyelid); as to claims 6 and 9, (fig. 1); and as to claims 10-15, 18, 20-26 and 29, (see above rejection).

Response to Amendment

Claim Rejections - 35 USC § 112

Applicant has canceled claims 7-9, 16-18 and 27-29. Therefore, the rejection has been withdrawn.

Response to Arguments

Applicant's arguments filed 5/9/03 have been fully considered but they are not persuasive.

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Applicant has amended claims 1, 10 and 21 to clarify that the registering placement means enable at least one of the lateral straddling member and the medial straddling member to be registerably placed **within** one or more of a **region** encompassed by a lateral angle of an eye, a region encompassed by a medial angle of that same eye, a lacus lacrimalis of the eye and the caruncula lacrimalis of the eye.

Specifically, Bosniak discloses a device for the external application with an internal cooperating means of iontophoresis in various parts of the eye. As can be seen in (fig. 1) and explained in the specification, the device overlies the eye and eyelids (34A and 34B), enabling a concentric array of electrodes (38A, 38B, 40A and 40B) to provide for transcutaneous electrical nuerostimulation. (Internal part of the eye) As clearly shown, the Bosniak reference specifically discloses the registered placement means which cooperates with the internal eye tissues, i.e. within the region of the lateral angle, medial angle, lacus lacrimalis and caruncula lacrimalis of the eye. All of the features are internal ocular structures, which clearly cooperate with the device of Bosniak.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action.

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In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communication from the examiner should be directed to Kevin C. Sirmons whose telephone number is (703) 306-5410. The examiner can normally be reached on Monday - Thursday from 6:30 am to 4:00 pm. The examiner can also be reached on alternate Fridays.

KCS

Kevin C. Sirmons
Patent Examiner
7/21/03

Brian L. Casler
BRIAN L. CASLER

SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700